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510(k) Summary of Safety and Effectiveness for the
PCA® Alumina 32mm Femoral Heads

FEB - 2 2007

Proprietary Name:	PCA® Alumina Femoral Heads
Common Name:	Artificial Hip Components
Classification Name and Reference	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis: Section 21 CFR 888.3353.
Regulatory Class:	Class II
Device Product Code(s):	LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented.
For Information contact:	Patricia Setti-LaPerch Regulatory Affairs Associate Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5938 Fax: (201) 831-4938 E-Mail: Patricia.LaPerch@stryker.com
Date Summary Prepared:	January 31, 2007

Device Description

PCA® taper (2° 52') femoral heads manufactured from Alumina ceramic (ASTM F603) with a Ti-6Al-4V alloy sleeves (ASTM F136) will be available in 32mm diameters. The femoral heads will be available with 0 (standard) and +5 offsets. The PCA® taper femoral heads are compatible with a range of CoCr alloy Howmedica Osteonics PCA® taper femoral stems. The subject components are also compatible for use with a wide range of acetabular components (shells and polyethylene inserts).

Intended Use:

The subject femoral heads are single-use devices intended for use in cemented or cementless total hip arthroplasty with various Howmedica Osteonics hip stems featuring the PCA® taper (2° 52') that are manufactured from CoCr alloy. They are not intended for use with any stem manufactured from Stainless Steel or Titanium alloy. They are also intended for use with any

compatible, currently available Howmedica Osteonics acetabular component featuring a polyethylene bearing surface.

Indications for Use

1) noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) rheumatoid arthritis (excepting the Osteolock™ HA Acetabular Cup and Peri-Apatite coated prostheses);
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Peri-Apatite coated prostheses are indicated only for primary uncemented total hip arthroplasty for items 1, 3, & 5 above when offered for sale in the USA.

Femoral head prostheses are indicated for use in cemented and cementless total hip arthroplasty, depending upon the indications of the acetabular and femoral stem components chosen.

Substantial Equivalence:

The PCA® Alumina Femoral Heads are substantially equivalent to the Alumina V40™ Femoral Heads (K023901), cleared by Howmedica Osteonics Corp., PCA Total Hip System - Cementless Use (K920831), cleared by Pfizer Hospital Products Group, Inc., and the V40™/C-Taper Adapter Sleeve (K003379), cleared by Howmedica Osteonics Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Orthopaedics
% Ms. Patricia Setti-LaPerch
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

FEB - 2 2007

Re: K063816
Trade/Device Name: PCA® Alumina 32 mm Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: II
Product Code: LZO
Dated: December 21, 2006
Received: December 22, 2006

Dear Ms. Setti-LaPerch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation

(21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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stryker
Orthopaedics

510(k) Number (if known): K063816

Device Name: PCA® Alumina Femoral Heads

Indications for Use

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Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Lourdes Rivera for MKM
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063816